



CERTIFICATE OF MAILING  
37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

March 22, 2004

Date

  
Shelley P.M. Fussey

**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Norman Barras and Ian David Cox

Serial No.: 10/693,328

Filed: October 24, 2003

For: Colon Cleansing Compositions and Methods

Group Art Unit: 1614

Examiner: Unknown

Atty. Dkt. No.: 4040.000600

**INFORMATION DISCLOSURE STATEMENT**

MAIL STOP MISSING PARTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record in the present case. Copies of the listed foreign patent documents and other art required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner. As the filing date of the present application is after June 30, 2003, copies of the listed U.S. patents are not included.

In accordance with 37 C.F.R §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.98 (a)(3), a concise explanation of the relevance of submitted article C11, as it is presently understood, is supplied. In accordance with 37 C.F.R. § 1.56(c), the translation of article C11 attached hereto is provided by a professional translator employed by Applicants' European representatives.

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits and hence is timely filed in accordance with 37 C.F.R § 1.97(b). No fees are due in connection with the filing of this Information Disclosure Statement. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Office should contact the undersigned representative to discuss deduction from Williams, Morgan & Amerson Deposit Account No. 50-0786/4040.000600.

Respectfully submitted,  
Williams, Morgan & Amerson, P.C.  
Customer No. 23720



Shelley P.M. Fussey, Ph.D.  
Reg. No. 39,458  
Agent for Applicants

10333 Richmond, Suite 1100  
Houston, Texas 77042  
(713) 934-7000

Date: March 22, 2004



I, ADRIAN PAUL BROWN, M.A., M.I.L., M.I.T.I., employed as a translator by Abel & Imray, Chartered Patent Attorneys, of 20 Red Lion Street, London WC1R 4PQ, U.K., do hereby declare that I am the translator of the following English text from the attached German text.

A handwritten signature in cursive script, appearing to read "A. P. Brown".

Adrian Brown

Dated this 19th day of March 2004

**35 075**

(Norgine)

**Klean-Prep**

Powder for intestinal lavage solution

**Composition:** 1 sachet (68.96 g) contains Macrogol (3350) 59 g, anhydrous sodium sulphate 5.685 g, sodium hydrogen carbonate 1.685 g, sodium chloride 1.465 g, potassium chloride 0.7425 g, corresponding to, in mmol/l:  $\text{Na}^+$  125,  $\text{K}^+$  10,  $\text{SO}_4^-$  40,  $\text{Cl}^-$  35,  $\text{HCO}_3^-$  20, PEG 17.6.

**Further constituents:** aspartame 0.0494 g, vanilla flavouring 0.3291 g.

**Indications:** Intestinal lavage before diagnostic tests, such as colonoscopy, and before intestinal surgical intervention.

**Contra-indications:** L 15 a

**Restrictions on use:** Acute inflammatory conditions of the gastrointestinal tract.

Patients under 18 years. Heart and kidney failure, and liver disease.

**Side-effects:** Occasional flatulence, nausea, and cramping stomach pains or vomiting.

**Toxicity:** L 15 (see chapter on Overdose)

**Dosage:** Over 4 to 6 hours, drink 4 litres of solution prepared from 4 sachets.

4 sachets each containing 68.96 g of powder in a plastic shaker 53.80

**Packs:** 48 sachets (12 x 4) each containing 68.96 g of powder in plastic shakers

**Lefax® chewable tablets / liquid / lozenges / drops**

see 60 322

Form PTO-1449 (modified)

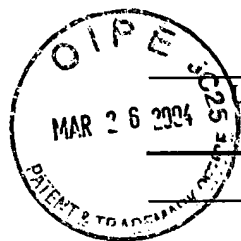
Atty. Docket No.  
4040.000600Serial No.  
10/693,328

## List of Patents and Publications for Applicant's

Applicant  
Barras and Cox

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:  
October 24, 2003Group:  
1614U.S. Patent Documents  
See Page 1Foreign Patent Documents  
See Page 1Other Art  
See Page 1 - 2

## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	6,048,901	April 11, 2000	Cleveland <i>et al.</i>	514	723	
	A2	5,274,001	Dec. 28, 1993	Borody	514	474	
	A3	5,077,048	Dec. 31, 1991	Kimura <i>et al.</i>	424	422	

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 03/037298 A2	May 08, 2003	PCT			
	B2	EP 0 397 689 B1	May 11, 1994	EP			
	B3	EP 0 436 061 B1	May 12, 1993	EP			
	B4	WO 89/05659	June 29, 1989	PCT			
	B5	WO 87/00754	Feb. 12, 1987	PCT			

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Andorsky <i>et al.</i> , "Colonic Lavage Solution (Polyethylene Glycol Electrolyte Lavage Solution) as a Treatment for Chronic Constipation: A Double-Blind, Placebo-Controlled Study," <i>Am. J. Gastroenterol.</i> , 85(3):261-265, 1990.
	C2	Braintree Laboratories, GoLYTELY®, product information, June 05, 2002.
	C3	Braintree Laboratories, NuLYTELY®, product information, June 05, 2002.
	C4	Clarkston <i>et al.</i> , "Oral Sodium Phosphate Versus Sulfate-Free Polyethylene Glycol Electrolyte Lavage Solution in Outpatient Preparation for Colonoscopy: A Prospective Comparison," <i>Gastrointestinal Endoscopy</i> , 43(1):42-49, 1996.
	C5	Davis <i>et al.</i> , "Development of a Lavage Solution Associated with Minimal Water and Electrolyte Absorption of Secretion," <i>Gastroenterology</i> , 78(5):991-995, 1980.
	C6	Evesa, Neohesperidine Dihydrochalcone (NHDC), product information, October 24, 2002.

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. 4040.000600	Serial No. 10/693,328
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Barras and Cox	
		Filing Date: October 24, 2003	Group: 1614
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1 - 2</i>	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C7	FLEET Company, Fleet Phospho-soda, Prescribing information - Oral Saline Laxative, July 29, 2002.
	C8	Fordtran <i>et al.</i> , "A Low-Sodium Solution for Gastrointestinal Lavage," <i>Gastroenterology</i> , 98:11-16, 1990.
	C9	Hammer <i>et al.</i> , "Studies of Osmotic Diarrhea Induced in Normal Subjects by Ingestion of Polyethylene Glycol and Lactulose," <i>J. Clin. Invest.</i> , 84:1056-1062, 1989.
	C10	Ingebo and Heyman, "Polyethylene Glycol-Electrolyte Solution for Intestinal Clearance in Children with Refractory Encopresis," <i>Am. J. Dis. Child</i> , 142:340-342, 1988.
	C11	Klean-Prep; Abstract 35 075, with translation.
	C12	LinTech, Contract Food Laboratory Service, July 31, 2002.
	C13	Merolli, "Flavor Enhancement: Taking a Closer Look," <i>Food Product Design</i> , February 1997.
	C14	MOVICOL, Australian product information, Health Answers Australia July 29, 2002.
	C15	Poon <i>et al.</i> , "Two Liters of Polyethylene Glycol-Electrolyte Lavage Solution Versus Sodium Phosphate as Bowel Cleansing Regimen for Colonoscopy: A Prospective Randomized Controlled Trial," <i>Endoscopy</i> , 23(7):560-563, 2002.
	C16	Puxty and Fox, "Golytely: A new Approach to Faecal Impaction in Old Age", <i>Age and Aging</i> , 15:182-184, 1986.
	C17	Regev <i>et al.</i> , "Comparison of Two Bowel Preparations for Colonoscopy: Sodium Picosulphate with Magnesium Citrate Versus Sulphate-Free Polyethylene Glycol Lavage Solution," <i>Am. J. Gastroenterol.</i> , 93(9): 1478-1482, 1998.
	C18	Telstra, GLYCOPREP-C, Australian product information, Health Answers Australia, June 05, 2002.
	C19	Thomas <i>et al.</i> , "Patient Acceptance and Effectiveness of a Balanced Lavage Solution (Golytely) Versus the Standard Preparation for Colonoscopy," <i>Gastroenterology</i> , 82:435-437, 1982.
	C20	Tolia, "Use of a Balanced Lavage Solution in the Treatment of Fecal Impaction," <i>J. Pediatr. Gastroenterol. Nutr.</i> , 7(2):299-301, 1988.
	C21	Ungerer & Company Manufactures of Fragrances, Flavor, Essential Oils, Aroma Chemicals, and Oleore, July 31, 2002.

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.